

**REMARKS**

The Office Action dated September 19, 2005, has been carefully considered. Claims 1, 27, 32, 33 and 35 have been amended. Claims 1, 4, 5, 7-33, 35, 36, 38-42 and 47 are in this application.

Claims 1, 4, 5, 7-33, 38-41 and 47 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claims 1, 27 and 32 have been amended to obviate the Examiner's rejection.

Claims 1, 4, 5, 7, 8, 10, 13-18, 20, 21, 27, 29, 30, 32, 35, 36, 38-42 and 47 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0027833 to Cleary et al., with the effective filing date of May 7, 2001.

Cleary et al. disclose a pharmaceutical composition for topical administration of a local anesthetic agent. The composition comprises (a) a therapeutically effective amount of a local anesthetic agent and (b) a pharmaceutically acceptable, nonliposomal carrier comprised of a monohydric alcohol, a penetration enhancer, and polymer, which may be a hydrophilic polymer, a hydrophobic polymer or a combination thereof. The composition can be in the form of a gel or a liquid that upon application to the body surface forms a film.

In contrast to Cleary et al., the invention defined by the present claims discloses a patch consisting of a single polymeric matrix layer. Accordingly, in the present invention, the patch is a solid film which can be easy to carry and the patch is applied to the skin during use. In contrast, Cleary et al. teach a liquid composition including monohydric alcohol which only when applied to the skin forms a film.

In addition, Cleary et al. disclose a conventional adhesive patch including a laminated composite of an upper backing layer and a drug layer. (See Cleary et al. ¶ [0023]) Accordingly, Cleary et al. do not teach or suggest a patch formed of a single polymeric layer. In another embodiment, Cleary et al. teach an embodiment without a backing layer that may include a hydrophobic layer. Applicants note that a hydrophobic layer is not water soluble and does not dissolve in the presence of water. In addition, Cleary et al. teach the addition of pressure sensitive adhesives (¶ [0095]). In contrast, the invention defined by the present claims is directed to a patch conformed to adhere to the skin without the use of an adhesive. Accordingly,

each of the embodiments of Cleary et al. teach away from the present invention of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer wherein the patch is configured so that the polymer matrix layer becomes tacky upon wetting for adhering the patch the skin without the use of an adhesive and the polymeric matrix layer dissolving or disintegrating in the presence of water for removing the patch from the skin upon rinsing said patch with water.

With regard to claim 16, Cleary et al. do not teach or suggest that a more cosmetic, dermatological and pharmaceutical active ingredients are encapsulated in nano-spheres or micro-spheres.

Accordingly, each limitation of the present claims is not found in Cleary et al. and the invention defined by the present claims is not anticipated by Cleary et al.

Claims 1, 4, 5, 9, 11-18, 20, 21, 26, 27, 29, 30, 32, 38, 42, and 47 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0107149 to Yang et al., with the effective filing date of October 12, 2001.

Yang et al. disclose a film product formed of a film forming polymer and polar solvent. The material is formed into a film and dried in a controlled manner to maintain non-self aggregating uniform heterogeneity. The film forming polymers can be water soluble, water-insoluble or a combination of water soluble or water-insoluble.

In contrast to the invention defined by the present claims, Yang et al. do not teach or suggest a patch consisting of a single polymeric matrix layer that is configured so that the matrix layer becomes tacky upon wetting for adhering the patch to the skin without the use of an adhesive. Rather, Yang et al. teach films to be orally administered by the use of mucoadhesive (§ [0155]). Alternatively, Yang et al. teach that the film can be dissolved when introduced into a liquid dosage (§ [0157]). However, nowhere is it taught or suggested in Yang et al. that the film can become tacky upon wetting for adhering the patch to skin without the use of an adhesive and that the film can be removed from the skin upon rinsing with water.

With regard to claim 16, Yang et al. do not teach or suggest that one or more cosmetic, dermatological and pharmaceutical active ingredients are encapsulated in nano-spheres or micro-spheres.

Accordingly, each limitation of the present claims is not found in Yang et al. and the invention defined by the present claims is not anticipated by Yang et al.

Claims 33, 35, and 36 were rejected under 35 U.S.C. §§ 102(a) and 102(e) as being anticipated by previously cited U.S. Patent Application Publication No. 2001/0007671 to Gueret, with an effective filing date of July 29, 1999.

Gueret '671 discloses a cosmetic, pharmaceutical, or dermatological patch which includes a composition including a hydrophilic gelling system in an aqueous phase. The hydrophilic gelling system includes at least one gellan gum and at least one other hydrocolloid. In contrast, the patch defined in the present claims does not include water. As described at ¶ [0007] of Gueret, a preferred object of the invention is to provide patches with high water content, into which various active agents may be incorporated, thereby imparting great softness, freshness, and/or coolness to the skin during application. Thus, Geuret '671 does not teach or suggest a patch consisting of a single polymeric matrix layer which does not include water. In addition, Gueret '671 discloses that the patch also includes reinforcement made of woven fabrics, nonwoven fabrics, and perforated films. Accordingly, the Gueret '671 patch is not soluble in water and the patch can not be removed by rinsing the area with water. Thus, Gueret '671 teaches away from the present invention of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer wherein the patch is configured so that the polymer matrix layer becomes tacky upon wetting for adhering the patch the skin without the use of an adhesive and the polymeric matrix layer dissolving or disintegrating in the presence of water for removing the patch from the skin upon rinsing said patch with water.

Accordingly, each limitation of the present claims is not found in Gueret '671 and the invention defined by the present claims is not anticipated by Gueret '671.

Claims 33, 35 and 36 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,419,935 to Gueret ("Gueret '935"), with the effective filing date of July 29, 1999.

Gueret '935 discloses a cosmetic skin treatment method which includes providing a patch configured to be used in both a cleansing mode and a treatment mode. The patch includes a polymeric matrix and a reinforcing member. The polymeric matrix includes at least one cosmetically active compound and at least one water-absorbent compound. The patch is

configured to adhere to dry skin and also to adhere to skin when at least one of the patch and skin are moistened. The method also includes selecting at least one of the cleansing mode and the treatment mode. When the cleansing mode is selected, the method further includes applying the patch to an areas of dry skin so that the polymeric matrix adheres to the skin for a time sufficient to allow at least one impurity in the area of skin to become attached to the polymeric matrix. Thereafter, the patch is removed from the area of the skin while said at least one impurity is attached to the polymeric matrix. When the treatment mode is selected, the method further includes moistening at least one of the patch and an area of the skin. Then, the patch is applied to the area of skin so that the patch adheres to the area of skin. After applying the patch, the cosmetically active compound is allowed to contact the area of skin. A cleansing and treatment patch is also disclosed.

In Gueret '935, the patch adheres to dry skin, thus it has an adhesive and the adhesive needs to be removed at the end of the treatment. Accordingly, the removal of the patches of Gueret '935 after treatment may cause irritation. In contrast, the invention defined by the present claims comprises affixing a patch comprising a water soluble polymeric matrix layer for adhering the patch to the skin without the use of adhesives. Further, the Gueret '935 patch swells in response to moisture and does not dissolve. Rather, only the active ingredients, that are entrapped in the patch, dissolve. As described at col. 3, lines 25-55 of Gueret '935, when moisture is applied to the patch by moistening the patch or by contacting the patch with moistened skin, the at least one water absorbent compound preferably absorbs moisture and forms a gel or a network of water-swollen fibers, into which the at least active compound is dissolved.

Accordingly, each limitation of the present claims is not found in Gueret '935 and the invention defined by the present claims is not anticipated by Gueret '935.

Claims 9, 11, 12, 19, 22-26, and 31 are rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent Application Publication No. 2003/0027833 to Cleary et al. in view of U.S. Patent Application Publication No. 2001/0007671 to Gueret.

Gueret '671 discloses a patch formed of a composition including a hydrophilic gelling system including a gellan gum and at least one other hydrocolloid. The patch does not

disintegrate when it is removed from the skin. (Col. 1, ¶ [0015]). Rather, the patch can be reused (¶ [0016]). Accordingly, with regard to claim 31, Gueret '671 teaches away from the present invention of a method for treating the skin comprising rinsing the skin with water for dissolving or disintegrating the polymer matrix layer and removing the patch by teaching that the patch does not disintegrate. Further Cleary et al. do not teach or suggest a method for treating the skin comprising rinsing the skin with water for dissolving or disintegrating the polymer matrix layer and removing the patch by teaching that a backing layer or hydrophobic layer are used which do not disintegrate.

Furthermore, Gueret '671 does not disclose or suggest that a patch consisting of a single polymeric matrix layer formed of a water-soluble film forming polymer consisting of one or more materials selected from the group consisting of maltodextrins, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Instead, Gueret '671 teaches a water insoluble hydrophilic gelling system including at least one gellan gum and at least one other hydrocolloid. There is no teaching or suggestion in Gueret '671 of the use of a water-soluble film forming polymer without the use of a gellan gum. Rather, Gueret '671 teaches the use of a gellan gum for forming a hydrophilic gelling system. As described above, both Cleary et al. and Gueret '671 do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer, which limitations of claim 1 are included in dependent claims 9, 19, 22-25. Further, neither Cleary et al. nor Gueret '671 teach or suggest that the patch becomes tacky upon wetting. Accordingly, neither Cleary et al. nor Gueret '671 teach the invention defined by the present claims and the invention defined by the present claims is not obvious in view of Cleary et al. or Gueret '671.

Claims 9, 19, 22-25, and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0107149 to Yang et al. in view of U.S. Patent Application Publication No. 2001/0007671 to Gueret.

As described above, Gueret '671 does not teach or suggest a patch consisting of a single polymeric matrix layer which does not include water. In addition, Gueret '671 discloses that the patch also includes reinforcement made of woven fabrics, nonwoven fabrics, and perforated

films. Rather, Thus, Gueret '671 teaches away from the present invention of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer wherein the patch is configured so that the polymer matrix layer becomes tacky upon wetting for adhering the patch to the skin without the use of an adhesive and the polymeric matrix layer dissolving or disintegrating in the presence of water for removing the patch from the skin upon rinsing said patch with water.

Accordingly, with regard to claim 31, Gueret '671 teaches away from the present invention of a method for treating the skin comprising rinsing the skin with water for dissolving or disintegrating the polymer matrix layer and removing the patch by teaching that the patch does not disintegrate. Further, Yang et al. do not teach or suggest that the film can become tacky upon wetting for adhering the patch to skin without the use of an adhesive and that the film can be removed from the skin upon rinsing with water.

Both Yang et al. and Gueret '671 do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer, which limitations of claim 1 are included in dependent claims 9, 19, 22-25. Further, neither Yang et al. nor Gueret '671 teach or suggest that the patch becomes tacky upon wetting. Accordingly, neither Yang et al. nor Gueret '671 teach the invention defined by the present claims and the invention defined by the present claims is not obvious in view of Yang et al. or Gueret '671.

Claims 9, 11, 12, 22-26, 28, and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0027833 to Cleary et al. in view of Gueret '935.

In Gueret '935, the patch adheres to dry skin, thus it has an adhesive and the adhesive needs to be removed at the end of the treatment.

In contrast, the invention defined by the present claims comprises affixing a patch comprising a water soluble polymeric matrix layer for adhering the patch to the skin without the use of adhesives. Further, the Gueret '935 patch swells in response to moisture and does not dissolve.

Further Cleary et al. do not teach or suggest a method for treating the skin comprising rinsing the skin with water for dissolving or disintegrating the polymer matrix layer and

removing the patch by teaching that a backing layer or hydrophobic layer are used which do not disintegrate.

Both Cleary et al. and Gueret '935 do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer, which limitations of claim 1 are included in dependent claims 9, 19, 22-25. Further, neither Cleary et al. nor Gueret '935 teach or suggest that the patch becomes tacky upon wetting. Accordingly, neither Cleary et al. nor Gueret '935 teach the invention defined by the present claims and the invention defined by the present claims is not obvious in view of Cleary et al. or Gueret '935.

Claims 9, 22-25, 28 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent Application Publication No. 2003/0107149 to Yang et al. in view of Gueret '935.

In Gueret '935, the patch adheres to dry skin, thus it has an adhesive and the adhesive needs to be removed at the end of the treatment.

In contrast, the invention defined by the present claims comprises affixing a patch comprising a water soluble polymeric matrix layer for adhering the patch to the skin without the use of adhesives. Further, the Gueret '935 patch swells in response to moisture and does not dissolve. Further, Yang et al. and Gueret '935 do not teach or suggest that the film can become tacky upon wetting for adhering the patch to skin without the use of an adhesive and that the film can be removed from the skin upon rinsing with water.

Both Yang et al. and Gueret '935 do not teach or suggest a patch consisting of a single polymeric matrix layer formed of a bioadhesive water-soluble film forming polymer, which limitations of claim 1 are included in dependent claims 9, 19, 22-25. Further, neither Yang et al. nor Gueret '935 teach or suggest that the patch becomes tacky upon wetting. Accordingly, neither Yang et al. nor Gueret '935 teach the invention defined by the present claims and the invention defined by the present claims is not obvious in view of Yang et al. or Gueret '935.


Claim 28 is rejected under 35 U.S.C. § 103(a) as being unpatentable over any of U.S. Patent Application Publication No. 2003/0027833 to Cleary et al. or U.S. Patent Application Publication No. 2003/0107149 to Yang et al.

As described above, Cleary et al. do not teach or suggest a method for treating the skin comprising rinsing the skin with water for dissolving or disintegrating the polymer matrix layer and removing the patch by teaching that a backing layer or hydrophobic layer are used which do not disintegrate. Further, Yang et al. and Cleary et al. do not teach or suggest that the film can become tacky upon wetting for adhering the patch to skin without the use of an adhesive and that the film can be removed from the skin upon rinsing with water.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

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